

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION,

Plaintiff,

v.

HETERO LABS LIMITED, HETERO
LABS LIMITED UNIT-V, HETERO
DRUGS LIMITED, HETERO USA, INC.,
AUROBINDO PHARMA LIMITED,
AUROBINDO PHARMA USA, INC.,
AUROLIFE PHARMA LLC, EUGIA
PHARMA SPECIALTIES LIMITED,
APOTEX INC., APOTEX CORP., MYLAN
PHARMACEUTICALS, INC., MYLAN
INC., MYLAN, N.V., and
BRECKENRIDGE PHARMACEUTICAL,
INC.,

Defendants.

Civil Action No. 17-3387 (ES) (JAD)

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ELECTRONICALLY***

[FILED UNDER SEAL]

**REPLY BRIEF IN SUPPORT OF DEFENDANTS MYLAN
PHARMACEUTICALS INC., MYLAN INC., AND MYLAN N.V.'S MOTION
TO DISMISS FOR IMPROPER VENUE, LACK OF SUBJECT MATTER
JURISDICTION, AND FAILURE TO STATE A CLAIM**

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INTRODUCTION

The Federal Circuit’s recent opinion *In re Cray* confirms that venue is improper as to the Mylan Defendants. *Cray* provides clear and unambiguous guidance regarding the meaning of the patent venue statute (28 U.S.C. § 1400(b)) and identifies three general requirements to the venue inquiry: “1) there must be a physical place in the district; 2) it must be a regular and established place of business; and 3) it must be the place of the defendant.” *In re Cray*, 871 F.3d 1355, 1360 (Fed. Cir. 2017). There are no other relevant considerations.

In this district, none of those three requirements is satisfied by any Mylan Defendant. There is no physical place in this district from which the business of any Mylan Defendant is carried out.

Celgene’s opposition is deeply flawed. Its legal arguments largely ignore the patent venue statute and *Cray* in favor of inapposite case law regarding personal jurisdiction, and its factual arguments stray far from the three simple requirements outlined by *Cray*. According to Celgene, the Court should ignore that lack of a required physical place in New Jersey from which the Mylan Defendants carry out their business and instead focus on irrelevant and vague concepts such as any Mylan entity’s purported “interactions” or “presence” in New Jersey.

Celgene also attempts to circumvent *Cray* by arguing that the acts and address of every single corporate entity owned by Mylan N.V. (a holding company) should be imputed to the Mylan Defendants — a self-serving argument that is extreme,

unreasonable, and unsupported. None of those entities was involved with the accused ANDA, nor does Celgene allege otherwise.

Cray is controlling law. Under *Cray*, the lack of a physical place in this district where any Mylan Defendant conducts business means that venue is improper in New Jersey. Accordingly, the Mylan Defendants should be dismissed.

SUPPLEMENTAL STATEMENT OF FACTS

I. No Mylan Defendant Has a Physical Place in New Jersey from Which It Operates Its Business

MPI does not have a fixed physical location in New Jersey. Supplemental Declaration of Keith Meckstroth (“Supp. Meckstroth Decl.”) ¶ 4. While thirteen of MPI’s 3,216 employees resided in New Jersey as of the filing of Celgene’s complaint, none of those residences serve as a place of business for MPI. None of the thirteen employees was required or instructed to live in New Jersey as part of their employment with MPI. *Id.* ¶ 5. Nor does MPI pay for any portion of the thirteen employees’ residences or contribute to any maintenance costs for the residences. *Id.* MPI does not require that any of the thirteen employees store materials in their residence or elsewhere in New Jersey. *Id.* MPI also does not pay for any secretarial or other support staff to work from the employees’ residences or elsewhere in New Jersey. *Id.*

None of MPI’s employees list their home addresses on their business cards. *Id.* ¶ 6. In addition, MPI does not list any of the addresses of the residences of the thirteen employees in any business, telephone, or other directory or website, nor has it placed its

name on a sign associated with or on any of the thirteen residences. *Id.*

Mylan N.V. similarly does not have a fixed physical location in New Jersey. *Id.*

¶ 10. Mylan N.V. has no employees in New Jersey. *Id.* ¶ 11.

Mylan Inc. does not have a fixed physical location in New Jersey. Four of Mylan Inc.'s employees reside in New Jersey and work remotely; however, none of those residences serve as a place of business for Mylan Inc. *Id.* ¶ 8. None of the four employees was required or instructed to live in New Jersey as part of their employment with Mylan Inc. *Id.* Mylan Inc. did not pay for any portion of the four employees' residences or contribute to any maintenance costs for the residences. *Id.* Mylan Inc. does not require that any of the four employees store materials in their residence or elsewhere in New Jersey. *Id.* Mylan Inc. also does not pay for any secretarial or other support staff to work from the employees' residences or elsewhere in New Jersey. *Id.*

None of the four employees list their home addresses on business cards. Mylan Inc. has not listed any of these home addresses in any business, telephone, or other directory or website, nor has Mylan Inc. placed a sign bearing its name associated with or on any of the four residences. *Id.* ¶ 9.

II. Non-Party Mylan Entities

Three non-party corporate entities currently owned by Mylan N.V. did at one point in time have a physical location in New Jersey.¹ These entities were located in

¹ Celgene incorrectly states that the Mylan Defendants have a physical location in Lambertville, New Jersey through Agila Specialties Inc. Opp. at 12. No Mylan entity
(continued...)

New Jersey prior to their acquisition. *Id.* ¶ 12. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] None of those physical locations have served as a place of business for the Mylan Defendants, and none of those Mylan entities was involved with the accused ANDA. [REDACTED]

[REDACTED]

[REDACTED]

III. The Mylan Defendants Operate as Separate Entities

Each Mylan Defendant has a separate corporate structure and operates as a distinct legal entity. Mylan Inc. and Mylan N.V. are holding companies, whereas MPI is a company engaged in R&D, manufacturing, marketing, and distribution of pharmaceutical products. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] No Mylan Defendant is an agent or alter ego of any other Mylan Defendant. [REDACTED]

(...continued from previous page)
has ever owned or occupied that location. Supp. Meckstroth Decl. ¶ 13.

[REDACTED]²

ARGUMENT

I. *In re Cray* Strictly Construes the Patent Venue Statute

In *Cray*, the Federal Circuit determined that the patent venue statute (28 U.S.C. § 1400(b)) ***requires*** a “***physical, geographical location*** in the district from which the business of the ***defendant*** is carried out.” *Cray*, 871 F.3d at 1362 (emphasis added). The Federal Circuit identified “three general requirements” to the “regular and established place of business” inquiry:

- (1) There must be ***a physical place*** in the district;
- (2) It must be a ***regular and established*** place of business; and
- (3) It must be the place ***of the defendant***.

Id. at 1360 (emphasis added). The “physical place” must be “settled certainly, or fixed permanently” in order to be “established.” *Id.* at 1362-63 (internal alterations and citations omitted). The residence of an employee in the venue is not enough. *Id.* at 1365-66. For example, a home office is not sufficient to establish a “place of the defendant.” Instead, the defendant must “establish or ratify the business,” by owning or leasing a place, operating out of a residence, or conditioning employment on residence. *Id.* at 1363. The mere setting up of an office or advertising a place of

² [REDACTED]

business in the district is also not enough; the defendant “must actually *engage in business*” from this *permanent, settled, physical, geographical location* that is *owned or ratified by the defendant*. *Id.* at 1364 (emphasis added).

II. Venue Is Improper as to All Mylan Defendants

Under *Cray*, venue is improper as to each Mylan Defendant. No Mylan Defendant has established or ratified a physical place in this district from which the business of any Mylan Defendant is carried out. *See id.* at 1362 (“The [venue] statute requires a ‘place,’ *i.e.*, ‘[a] building or a part of a building set apart for any purpose’ or ‘quarters of any kind’ from which business is conducted.”) (citation omitted).

Plaintiffs agree that Federal Circuit law controls the substantive application of § 1400(b). Nonetheless, they contend that Third Circuit law controls procedural aspects, such as the pleading standard and burden of proof. (Pl. Opp. at 8). Plaintiffs are wrong. Because § 1400(b) is a patent-specific statute, it is governed by Federal Circuit law:

[A] procedural issue that is not itself a substantive patent law issue is nonetheless governed by Federal Circuit law if the issue pertains to patent law, if it bears an essential relationship to matters committed to [the Federal Circuit’s] exclusive control by statute or if it clearly implicates the jurisprudential responsibilities of [the Federal Circuit] in a field within its exclusive jurisdiction.

Midwest Indus. v. Karavan Trailers, 175 F.3d 1356, 1359 (Fed. Cir. 1999). The inquiry ends there.

The Federal Circuit evaluates “[v]enue ... based on the facts alleged in the well-

pleaded complaint,” *Hoover Grp., Inc. v. Custom Metalcraft, Inc.*, 84 F.3d 1408, 1410 (Fed. Cir. 1996), and plaintiff bears the burden as to venue. *See* Wright, Miller *et al.*, Federal Practice and Procedure §3826 (3d ed. 2017) (“[T]he weight of judicial authority appears to be that when the defendant has made a proper objection, the burden is on the plaintiff to establish that the chosen district is a proper venue.”).³ But regardless of where the burden lies, venue is improper here.

A. MPI Does Not Have a Physical Place in New Jersey from Which It Operates Its Business

Venue in this district is improper as to MPI. MPI does not have a business address, building, office, or quarters of any kind in New Jersey. Thus, the requirements of *Cray* are not and cannot be met.

Celgene does not dispute that MPI does not own or lease an office in New Jersey. Instead, Celgene incorrectly argues that the residences of thirteen MPI employees in New Jersey satisfy the “physical location” requirement of the venue analysis. *Opp.* at 7-8. *Cray* expressly rejected that argument:

As the statute indicates, it must be a place *of the defendant*, not solely a place of the defendant’s employee. Employees change jobs. Thus, the defendant must establish or ratify the place of business. It is not enough that the employee does so on his or her own.

³ At the very least, there is a split of authority as to who bears the burden of proof on an objection to venue. *See Raytheon Co. v. Cray, Inc.*, No. 15-1554, 2017 WL 2813896, at *2–3 (E.D. Tex. June 29, 2017) (discussing the various views of the courts). Many courts have held that “the burden to establish proper venue lies with the plaintiff.” *Id.* at *3.

Cray, 871 F.3d at 1363 (emphasis in original).

Here, MPI does not own, lease, possess, or exercise control over the New Jersey residences occupied by its employees. Nor does MPI condition employment on residence in New Jersey or hold any of those residences out as a place of business. Thus, under *Cray*, the fact that thirteen MPI employees happen to live in New Jersey is immaterial and does not transform their personal homes into places of business of MPI. *Id.* at 1366. (“The fact that ‘the defendant’s employee owns a home in which he carries on some of the work that he does for the defendant’ was insufficient to establish venue.”) (citation omitted).

B. Mylan N.V. and Mylan Inc. Do Not Have a Physical Place in New Jersey from Which They Operate Their Business

Venue is improper as to Mylan N.V. Mylan N.V. does not occupy a building, office or quarters of any kind in New Jersey, does not have a business address in New Jersey, and has no employees who reside in New Jersey. Thus, the requirements of *Cray* are not and cannot be met with respect to Mylan N.V.

Venue over Mylan Inc. is also improper. Mylan Inc. does not have a physical place in this district from which it engages in business. Mylan Inc. employs four individuals who reside in New Jersey and work remotely. Their employment is not conditioned on residence in New Jersey, and Mylan Inc. does not pay for any portion of their New Jersey residence. Supp. Meckstroth Decl. ¶ 8. To the extent Celgene attempts to argue that the residences of those individuals should be considered

“physical locations” of Mylan Inc., that argument fails for the same reasons discussed above regarding the thirteen MPI employees residing in New Jersey.

III. Celgene’s Attempts to Argue that the Mylan Defendants Established or Ratified a Physical Place of Business in New Jersey Are Incorrect

Celgene argues incorrectly that the Mylan Defendants have a physical location in New Jersey. Opp. at 11-13. However, none of Celgene’s so-called “facts” is probative of whether any Mylan Defendant has a “regular and established place of business.”

A. The Physical Address of Non-Party Entities Is Irrelevant to Whether Venue is Proper Over the Mylan Defendants

Celgene’s conclusory assertion that “Mylan has brick-and-mortar offices in New Jersey” (Opp. at 12) is wrong. As discussed above, none of the Mylan Defendants conducts business out of a physical place in New Jersey. Each of the non-party entities identified by Celgene as having “brick-and-mortar offices” or telephone listings in New Jersey — *i.e.*, Mylan entities that Celgene did **not** name as defendants (Mylan Specialty L.P., Agila Specialties Inc., and Mylan Laboratories Inc.) — are separate corporate entities from the Mylan Defendants. None was involved in the submission of the accused ANDA. Celgene does not allege otherwise in the Complaint. Thus, the physical location of non-party entities has no bearing on the venue inquiry. *See Papercraft Corp. v. Procter & Gamble Co.*, 439 F. Supp. 1060, 1062 (W.D. Pa. 1977) (“[T]his court cannot subject the parent to venue within this district solely because the parent corporation owns a profitable subsidiary which is doing business here.”); *Am. Standard, Inc. v. Pfizer, Inc.*, No. 83-834-WKS, 1984 WL 63632, at *1 (D. Del. Apr. 26, 1984) (“I

cannot, in the absence of some justifying evidence, ignore the separate corporate identities of these two corporations and attribute the allegedly infringing acts of [the subsidiary] to Pfizer for venue purposes.”).

Also, Celgene’s statements regarding the three “brick-and mortar” addresses in New Jersey are incorrect. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. Thus, none of those offices can satisfy the “physical place” requirement.

Setting aside the lack of an operative physical place, Celgene further attempts to circumvent *Cray* by arguing that “Mylan’s disregard for corporate form supports [the conclusion that] the activities of any one entity [owned by Mylan N.V.] can be attributed to them all.” Opp. at 11. However, Celgene’s argument that venue is appropriate over a corporate entity due to the lack of formal separation from a related corporate entity is subject to a “high standard.” *Symbology Innovations, LLC v. Lego Sys., Inc.*, No. 2:17-CV-86, 2017 WL 4324841, at *10 (E.D. Va. Sept. 28, 2017) (determining venue was improper over the parent corporation despite a subsidiary that operated three retail stores within the district). Courts consider a number of factors, including whether corporations have “separate finances, assets, officers, and records.” *Id.* Courts have also looked at whether the corporations maintain separate finances, and whether there are differences in the officers and directors between the two companies. *See id.*

Here, each of the non-party entities Celgene identifies is a distinct corporate entity from any of the Mylan Defendants. Supp. Meckstroth Decl. ¶ 12. [REDACTED]

[REDACTED]

[REDACTED]

⁴ *Id.* ¶ 12; *see Symbology Innovations*, 2017 WL 4324841, at *10 (stating courts are “more likely to find separate corporate entities if the officers and directors of the parent and the subsidiary are not all the same”) (internal citation omitted).

The cases cited by Celgene (Opp. at 9) support Mylan’s position and state: “[t]he corporate form is not readily brushed aside.” *Minn. Mining & Mfg. Co. v. Eco Chem., Inc.*, 757 F.2d 1256, 1264 (Fed. Cir. 1985).⁵ Disregard of the corporate form is rare and occurs only “on grounds of fundamental equity and fairness.” *Id.* (citation omitted). Celgene must show that “the parent *so dominated* the subsidiary that it had *no separate existence* but was merely a conduit for the parent.” *Patent Incentives, Inc. v. Seiko Epson Corp.*, C.A. No. 88-1407, 1988 WL 92460, at *6 (D.N.J. Sept. 6, 1988) (emphasis added)

⁴ [REDACTED]

⁵ The facts of *Minn. Mining & Mfg.* are readily distinguishable. A closely-held corporation was dissolved after suit was filed against it for infringement. The founders of the dissolved corporation established a new business in which: stockholders of the old corporation exchanged their old shares for new shares in the new corporation; checks written out to the old corporation were deposited in the new corporation’s account; and all of the assets of the old corporation, including customer lists, trademarks, and inventory were converted to the assets of the new corporation. The Federal Circuit upheld the District Court’s decision to find the new business and the owners “successors in interest and alter egos” of the dissolved corporation. *Id.* at 1259.

(citation omitted).

Notably, none of the exhibits attached to Celgene's Opposition papers show domination over a subsidiary such that it had no separate existence. Importantly, none show that the physical places in New Jersey identified by Celgene can be imputed to any Mylan Defendant. For example, the sharing of the Mylan brand, www.mylan.com, press releases, logo, and customer service email address (Opp. at 10-11) are irrelevant. Those facts, at best, show that Mylan N.V. reasonably fosters coordination, shared resources, and branding amongst its separate subsidiaries.

Shared office space or an "overlap in Mylan's leadership and projects" similarly does not show disregard for the corporate structure. *See Symbology Innovations*, 2017 WL 4324841, at *10 ("[E]ven where the parent corporation controls a subsidiary's operations and the companies share a unitary business purpose, the subsidiary's presence in the forum cannot be imputed to the parent company so long as they maintain formal corporate separateness.") (citation omitted). Correspondence with the FDA regarding FDA draft guidance sent on behalf of Mylan Inc. and signed by Mylan N.V. (Opp. at 11) shows only that the related entities leverage expertise within the Mylan N.V. family. The request for consolidation of several Mylan entities for purposes of GDUFA II was expressly contemplated by the FDA and shows only that the Mylan entities are affiliated. "Under GDUFA II, it is anticipated that ***affiliated companies*** will be grouped together and counted as a single entity for purposes of assessing the program fee." *See* Ex. A at 2382 (emphasis added).

Celgene's alter-ego theory rests on hyperbole, not facts. There is no evidence that the addresses of non-party entities should be imputed to any Mylan Defendant.

B. The Locations and/or Actions of a Mylan Defendant Do Not Impute to Any Other Mylan Defendant

Celgene also argues throughout its Opposition that the actions of MPI impute to the other Mylan Defendants. Opp. at 2-8, 12, 14, 22, 25-29. Celgene's argument fails for the same reasons discussed above regarding non-party Mylan entities. [REDACTED]

[REDACTED] Supp. Meckstroth Decl. ¶ 3. Celgene's description of all three Mylan Defendants as part of a "tight-knit corporate family" (Opp. at 28) is simply insufficient to impute the actions of a distinct corporate entity to another distinct corporate entity.

C. Neither Clinical Trials Sponsored by Mylan Inc. Nor Advertising on Clinicaltrial.gov Are A Physical Place

Celgene argues that clinical trials sponsored by Mylan Inc. that occurred in New Jersey comprise physical places in the district belonging to the Mylan Defendants. Opp. at 12. Celgene articulates no basis for its position beyond its conclusory argument that a clinical trial sponsored by Mylan Inc. somehow amounts to all Mylan Defendants' "regular and established" physical place. Notably, Celgene does not claim that any Mylan Defendant owns or leases the locations of the clinical trials. Nor does Celgene argue that the personnel used to run the clinical trials are employed by any Mylan Defendant. Nor does Celgene claim that any Mylan Defendants' name appears on the building where the clinical trials are run, or that any Mylan Defendant lists the address

of the location as a place of business. In fact, the information provided in the documents cited by Celgene show that the two clinical studies in New Jersey concluded in 2014 and 2015, long before this action commenced. ECF No. 88 at Exs. 30, 31.

Celgene even goes so far as to argue that Mylan “advertises its New Jersey presence through clinicaltrials.gov” Opp. at 16-17. Even if it were relevant, such a “presence” does not establish the physical, geographical location required by *Cray*.

There is simply no legal or factual basis for Celgene’s argument. *See Phillips v. Baker*, 121 F.2d 752, 756 (9th Cir. 1941) (“A ‘regular place of business’ is, obviously, a place where such business is carried on ‘regularly’ and not merely temporarily, or for some special work or particular transaction.”).

D. Celgene’s Laundry List of Enumerated Arguments Regarding Venue Ignore the Plain Language of *Cray*

Celgene’s Opposition provides an assortment of other arguments that purport to address the *Cray* factors. Opp. at 12-17. Each of those arguments ignores or misunderstands the plain requirements of *Cray* and should be rejected.

1. “Targeted Interactions” with New Jersey are Irrelevant

Celgene argues generally that “targeted interactions with New Jersey” show that the Mylan Defendants have physical places that are “regular and established.” Opp. at 13. However, not one of the purported “interactions” provides proof that venue over the Mylan Defendants is proper in this district. For example, Celgene argues that a Mylan web page shows that “Mylan partners with” persons in New Jersey (Opp. at 13,

Ex. 4 at 2), but the web page makes no mention of New Jersey. Likewise, Celgene's allegations of a "special website for New Jersey" (Opp. at 16, Ex. 50) does not offer anything for sale on the site. *Cray* has held that advertisements are only relevant "to the extent they indicate that the defendant itself holds out a place for its business," which the site does not do. *Cray*, 871 F.3d at 1363. [REDACTED]

[REDACTED]

[REDACTED] Opp. at 13-14. Yet neither of those facts identifies a physical place in New Jersey from which any Mylan Defendant conducts business.

Grasping at straws, Celgene points out that a patent assigned to Mylan Inc. shows that one of the named inventors lived in New Jersey, that non-party corporate entity Mylan Specialty made payments to physicians in New Jersey, and that another non-party entity, Mylan Institutional Inc., and MPI made payments for food and beverage purchases in New Jersey. Again, neither of those "facts" is meaningful to the *Cray* venue analysis. And Celgene fails to articulate any reason to the contrary – because it cannot.

2. Business Registrations and Revenue in New Jersey are Irrelevant

Celgene argues that business registrations by the named Mylan Defendants and other non-party corporate entities support the conclusion that "Mylan's *operations* in New Jersey are 'regular and established.'" Opp. at 14 (emphasis added). First, Celgene

cites *no* authority finding that registration confers venue. That is not surprising because it does not exist. Second, Celgene's argument reflects a fundamental misunderstanding of the *Cray* venue analysis. The focus of *Cray* is whether a "physical place" of the defendant is "regular and established." *Cray*, 871 F.3d at 1360. Celgene's analysis incorrectly focuses on "operations" rather than a "physical place." As stated in *Cray*, "there must still be a physical, geographical location in the district from which the business of the defendant is carried out." *Id.* at 1362. Further, "[t]he statute requires a 'place,' *i.e.*, [a] 'building or part of a building set apart for any purpose' or 'quarters of any kind' from which business is conducted." *Id.* "Operations" are not physical, geographic locations. Nor are "operations" a proxy for a place. Celgene's argument that "operations" are relevant to the *Cray* factors is plainly incorrect.

Celgene also argues that "Mylan derives substantial revenue from New Jersey," and "Mylan generics saved New Jersey \$700 million." Opp. at 15. Those facts do not relate to a physical place in New Jersey from which the business of any Mylan Defendant is carried out. Thus, they are not probative of any *Cray* factor.

3. Previous Litigation in this District, "Presence" in New Jersey, and Stale Leaseholds Are Irrelevant

Celgene argues that "Mylan . . . has a frequent and established presence in this Courthouse." *Id.* The Mylan Defendants' appearances in litigations filed in this district do not demonstrate a "regular and established place of business." No Mylan Defendant owns or leases the Courthouse, and no part of any Courthouse in this

district is set aside for the Mylan Defendants to carry out their business.

Celgene also argues that the Mylan mission statement, advertising, job postings and “regular presence in New Jersey” are relevant to the *Cray* analysis. *Id.* at 16. Those arguments are not specific to any Mylan Defendant; nor are they probative of whether a physical place in New Jersey was established or ratified by any of the Mylan Defendants.

Celgene further argues that Mylan Inc. leased property in New Jersey in 2009 and 2010. Tellingly, Celgene fails to cite *any* authority as to how that fact has any bearing on whether venue is proper over Mylan Inc. in a case filed in 2017.

In sum, Celgene’s laundry list of arguments is unavailing because each ignores or misunderstands *Cray*. None of them evidence a physical place in this district from which the business of any Mylan Defendant is carried out.

IV. Celgene’s Insistence That the Court Should Consider Factors Not Identified by the Patent Statute is Misguided

Celgene insists incorrectly that the Court should consider issues that are unrelated to the venue statute. *Opp.* at 18. Importantly, Celgene relies on case law pertaining to personal jurisdiction, *not* venue, to support its argument. Thus, Celgene urges the Court to adopt an approach to venue that *Cray* expressly cautioned against: “Courts should be . . . careful not to conflate showings that may be sufficient for other purposes, *e.g.*, personal jurisdiction or the general venue statute, with the necessary showing to establish proper venue in patent cases.” *Cray*, 871 F.3d at 1361.

As discussed at length in *Cray*, the correct venue analysis focuses exclusively on the express language of the venue statute, not the Hatch-Waxman Act or other purported concerns. “We stress that the [venue] analysis *must* be closely tied to the language of the statute.” *Id.* at 1362 (emphasis added).

V. MPI Has Not Committed an “Act of Infringement” in New Jersey

Celgene agrees that the sole “act of infringement” alleged in the Complaint is MPI’s submission of the accused ANDA. It is undisputed that MPI’s ANDA was *not* submitted in New Jersey. Those facts alone establish that venue is improper in this district simply because no Mylan Defendant has committed an act of infringement in New Jersey.

Celgene argues incorrectly that MPI’s mailing of the notice of patent certifications to Celgene in New Jersey and speculative allegations of future infringement by the Mylan Defendants are relevant to the venue analysis. Opp. at 3-6. Those arguments are either entirely unsupported or rely exclusively on case law regarding personal jurisdiction and facts relevant to personal jurisdiction.⁶ This is

⁶ The one possible exception is Celgene’s reliance on *Bristol-Myers Squibb Co. v. Mylan Pharm. Inc.*, No. 17-379-LPS, 2017 WL 3980155 (D. Del. Sept. 11, 2017), which addressed the issue of venue, not personal jurisdiction. However, the *BMS* opinion relied heavily on case law regarding personal jurisdiction for purposes of its venue analysis. In accordance with *Cray*, venue is independent of and separate from personal jurisdiction. Moreover, the venue analysis is “closely tied to the language of the statute.” *Cray*, 871 F.3d at 1362. Thus, the *BMS* case is inconsistent with *Cray*, which is now controlling law. *BMS* issued before *Cray* and without the benefit of the guidance provided in *Cray* regarding how to properly analyze venue in patent cases.

another example of Celgene urging the Court to ignore *Cray*'s instruction to read the venue statute narrowly.

When read narrowly, as required by *Cray*, the meaning of the venue statute is quite clear. Section 1400(b) is drafted in the past tense: “[a] civil action for patent infringement may be brought . . . where the defendant *has committed* acts of infringement” *Cray*, 871 F.3d at 1361 (emphasis added).⁷ Verb tense is material to understanding “a statute’s temporal reach.” *Carr v. U.S.*, 560 U.S. 438, 447-48 (2010) (citation omitted); *Cullen v. Pinholster*, 563 U.S. 170, 182 (2011) (“past tense” is “backward-looking”). The only alleged act of infringement committed by the Mylan Defendants is submission of the ANDA. That act was committed in West Virginia, not New Jersey. That fact is dispositive of the venue analysis.

VI. Venue Is Not Proper Over Mylan N.V. Because It Is a Foreign Corporation

Celgene argues that venue is proper in New Jersey over Mylan N.V. simply because it is a non-U.S. corporation. Opp. at 17-18. That argument entirely ignores patent venue statute as well as the allegations in the Complaint. 28 U.S.C. § 1400(b) limits venue to “where the defendant resides, or where the defendant has committed

⁷ Celgene’s focus on “future” acts is also problematic for at least a second reason: if MPI prevails in this litigation, there would be no future infringing activity (*i.e.*, the patents’ claims would be deemed invalid and/or not infringed); and if MPI does not prevail, there also would be no future infringing activity because MPI would be enjoined from selling its ANDA product until patent expiry. Thus, relying solely upon “future” acts is wrong in this context.

acts of infringement and has a regular and established place of business.” Celgene’s infringement claim against Mylan N.V. is viable *only* if the act of submitting the accused ANDA, which was committed by MPI, is imputed to Mylan N.V. Assuming that it does impute (which it should not, as discussed in Section B.2.), then venue over Mylan N.V. is appropriate only in West Virginia. Mylan N.V.’s status as a non-U.S. corporation does not mean that the patent venue statute is inapplicable.⁸

VII. The Court Should Deny Celgene’s Alternative Request for Venue Discovery

Celgene’s request for venue-related discovery should be denied. *Cray* outlined the only three factors relevant to the “regular and established place of business” analysis. The facts of record in the Motion address each of those factors. Yet Celgene contends that broad, additional discovery is needed into irrelevant issues such as “Mylan’s contracts with New Jersey-based entities” and “Mylan’s overall new Jersey footprint.” Opp. at 21-22. Such costly and far-flung venue discovery would be a waste of time and resources. *See Symbology Innovations*, 2017 WL 4324841, at *12 (denying a request for venue-related discovery because “[Plaintiff] fails to identify any source of information or fact that would change the Court’s analysis of whether [Defendant] has a regular and established place of business in this District.”). Celgene’s request to

⁸ Celgene argues incorrectly that MPI “effectively conceded that venue is proper for a foreign corporation under § 1391(c).” Opp. at 17 (citing to an unrelated Complaint filed by MPI). There, the non-U.S. corporation named as a defendant owned the ANDA, and the U.S. corporation also named as a defendant was the authorized U.S. agent for the ANDA. Those facts are not present here.

engage in a fishing expedition of irrelevant facts should be denied.

VIII. Celgene Failed to State A Claim Against Mylan Inc. and Mylan N.V. Under § 271(e)

As discussed in the Motion, MPI is the only Mylan Defendant who “has committed” any act of alleged infringement. Neither Mylan Inc. nor Mylan N.V. submitted the ANDA. Thus, neither entity meets to express requirement of 35 U.S.C. 271(e) and should be dismissed.

To circumvent that requirement, Celgene relies on allegations that MPI and Mylan Inc. are “agents and/or alter egos of Mylan N.V.” The Court need not give any weight to self-serving legal conclusions. *Armano v. Martin*, 157 F. Supp. 3d 392, 399 (D.N.J. 2016). Celgene also relies on general conclusory allegations regarding the Mylan Defendants (Opp. at 27), but none show fraudulent activity or corporate misfeasance that would rise to the level of piercing the corporate veil such that the actions of one corporation should be imputed to another.

IX. Celgene Concedes Its Claims Under 35 U.S.C. §§ 271(a)-(c) are Not Independent Claims and Lack Subject Matter Jurisdiction

Celgene admits that “there are no §§ 271(a)-(c) ‘claims’ to dismiss” because the allegations regarding those subsections of § 271 “are merely referenced as part of the § 271(e)(2) claims.” Opp. at 23. Having conceded that point, Celgene nonetheless argues that allegations regarding §§ 271(a)-(c) should be read as allegations of “future infringing activities.” *Id.* at 24. As detailed in the Motion, Celgene’s argument lacks

merit and has been expressly rejected in this district. ECF No. 56-1 at 12. Accordingly, Celgene's claims of infringement under §§ 271(a)-(c) should be dismissed for lack of subject matter jurisdiction.

X. Celgene Suffers No Prejudice from Dismissal, and No Improper Loss of Efficiency Would Result

Dismissal of the Mylan Defendants from this action for lack of venue is the appropriate remedy. Celgene argues that the claims against the Mylan Defendants should remain in New Jersey because concerns regarding judicial efficiency should override the requirements of the venue statute. That argument is inconsistent with *Cray*. In addition, dismissal of the Mylan Defendants will not unduly harm the interests of judicial efficiency. Congress provided for multidistrict litigation for this exact purpose, *i.e.*, to promote judicial efficiency where the venue statute requires related cases to be filed in different district courts. *See* 28 U.S.C. § 1407.

If, instead, the Court believes transfer is appropriate, then the Northern District of West Virginia should be the transferee district.

CONCLUSION

For the foregoing reasons and the reasons set forth in the Motion, MPI, Mylan Inc., and Mylan N.V. respectfully request that this Court dismiss Counts IV, IX, XIV, and XIX of Celgene's Complaint for improper venue, lack of subject matter jurisdiction, and failure to state a claim upon which relief can be granted.

Respectfully submitted,

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